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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,885	04/25/2005	Marc Koska	088398-9002	1376

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EXAMINER
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SCHELL, LAURA C

ART UNIT	PAPER NUMBER
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3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/18/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/517,885

Applicant(s)

KOSKA, MARC

Examiner

Laura C. Schell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1, and hence all dependent claims 2-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The last four lines of claim 1 are not clear in what Applicant is attempting to claim. In particular, "and a second guide part operative ..." which then picks up at "and following release of a force urging the second member to expose the needle" is not clear. From the phrasing, it would appear that the phrase that starts "and following release of a force" is still trying to refer to "a second guide part operative". It is suggested that applicant try re-phrasing these last four lines for better clarity.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 12-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Vaillancourt (US Patent No. 5,591,138). Vaillancourt discloses a needlestick

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prevention device (Fig. 11) for an injection device having a hollow needle, comprising: a sheath having a first member (13) for attachment to the injection device and a second member (17) slidable longitudinally relative to the first member to expose or to cover the needle, and a spring (Fig. 6, 19) biasing the second member to cover the needle, the first and second members having interengaging guides and locks, characterized in that the guides include a first guide part (22) operative to allow free longitudinal sliding movement of the second member relative to the first member, and a second guide part (25) operative on movement by manual relative rotation of the first and second members (col. 6, lines 45-47 discloses that in order to move the projection (21) from the second guide part requires manual rotation. Col. 8, lines 41-50 disclose that upon release of a force, the spring urges the pin (21) down the first guide member and the spring urges the pin into the lock (area 35) by means of the cam in part 35. The spring is thus also urging the second member to cover the needle and to operate the lock to retain the second member covering the needle. Please note that Applicant's claim language does not state an order in which the manual rotation and the releasing of force must occur.) and following release of a force urging the second member to expose the needle, in which the spring urges the second member to cover the needle and to operate the lock to retain the second member covering the needle.

Vaillancourt further discloses that the guide comprises at least one groove (22) on the first member and a corresponding projection (21) on the second member. Vaillancourt also discloses that the second member slides inside the first member (see Figs. 2 and 3). Vaillancourt further discloses that the spring comprises a compression

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spring acting between the inner end of the second member and an abutment of the first member (Fig. 6). Vaillancourt further discloses that the injection device is a syringe comprising a barrel (col. 5, lines 62-65). Vaillancourt further discloses that the prevention device is secured to the hub of the needle by a luer connector (Fig. 25, 59; also see col. 12, lines 33-36).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaillancourt (US Patent No. 5,591,138). Vaillancourt discloses that the grooves are provided on the interior surface of the 1st member, the projection on the exterior surface of the second member (Figs. 1-5), that the second member must be rotated for the projection to move, that the lock (Fig. 5, 27) comprises a permanent locking recess in which the projection is received, that there is a temporary locking recess provided (Fig.

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14, 38) and that in one of the temporary locking recesses the second member is slightly less extended from the first member than when in the permanent locking position (Fig. 14). Vaillancourt, however, does not disclose that the groove is provided on the radially exterior surface of the second member and that the projections are on the radially interior surface of the first member, in fact, Vaillancourt discloses the exact opposite as described above. It would have been obvious to one having ordinary skill in the art at the time of the invention to have reversed the members on which the groove and projection are placed, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-21 have been considered but are moot in view of the new ground(s) of rejection.

In particular, as discussed above, Fig. 11 discloses a locking recess (in area 35) in which the projection (21) is moved into by the force of the spring, as when the force against the sheath (17) is released, the spring biases the sheath and consequently moves the projection down groove (22) where it hits area (35) and the spring's force forces the projection into the locking recess. Also, since applicant's wording of claim 1 does not specify the order in which the manual rotation and the release of the force happen, the disclosure of manually moving the projection from (25) to the top portion of (22) is an acceptable interpretation of the claim language as read upon Vaillancourt, see rejection above.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

